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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,732	11/01/2001	Leif Andersson	2183-4951US	6509

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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,732	ANDERSSON ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-9,36 and 39-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-9,36 and 39-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 June 2001* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/05; 3/06*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *2/28/06* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/2005 has been entered.

Claims 1-4, 6-9, 36 and 39-45 are currently pending and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/27/05 and 3/6/06 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-9, 36 and 39-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

> A method for selecting a male pig (sire) for breeding by identifying a male pig having a quantitative trait locus (QTL) associated with decreased fat deposit such that when said male pig is used in a breeding program, the offspring of the male pig that inherit said QTL from the male pig have decreased fat deposit compared to controls (i.e., the QTL is paternally imprinted in the offspring that inherit the QTL from said male pig) wherein the identification of said male pig comprises:
> identifying the presence of the QTL associated with decreased fat deposit by detecting one or more genetic markers selected from the group consisting of genetic markers linked to the QTL on chromosome 2 of the male pig, genetic markers in linkage disequilibrium with the QTL on chromosome 2 of the male pig, genetic markers within the QTL on chromosome 2 of the pig that represent the actual causal mutation that results in reduce fat deposition, and combinations of any thereof,
> wherein the location of the QTL is indicated by a genomic region comprising the genetic markers Swr2516, Swc9, S22623 and Swr783 on chromosome 2 of the male pig, and
> wherein the QTL is present on chromosome 2 of the male pig at position 2p1.7,
> wherein the identification of a male pig having the QTL associated with decreased fat deposit selects the male pig for breeding;

does not reasonably provide enablement for the full breadth of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

> *Wands* states on page 1404,
> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

First, the Examiner would like to acknowledge the interview with Applicant Michel Georges and Applicants' representative Yury Colton on February 28, 2005, a summary of which is attached to this Office Action. The interview was very helpful to the Examiner's understanding of the invention. In light of the knowledge gained from the 2/28/05 interview, the Examiner has reconsidered the disclosure of the instant application and determined that the with respect to selecting animals comprising a paternally imprinted QTL, the specification only has an enabling disclosure for selecting a male pig for breeding by identifying a male pig having a quantitative trait locus (QTL) associated with decreased fat deposit (as indicated above) such that when said male pig is used in a breeding program, the offspring of the male pig that inherit said QTL from their father have decreased fat deposit compared to controls (i.e., the QTL is paternally imprinted in the offspring that inherit the QTL from the male pig). It is noted that the specification also provides an enabling disclosure for using the male pig having the QTL indicated above in a breeding program such that the offspring of the male pig that inherit the QTL from their father also have decreased fat deposit (i.e., the QTL is paternally imprinted in the offspring that inherit the QTL from their fathers).

The instant specification discloses that applicants have identified a paternally imprinted QTL that is associated with decreased fat deposit in pigs wherein the paternally imprinted QTL is located on chromosome 2 at position 2p1.7. The specification further discloses that the actual

causal mutation that causes the decreased fat deposit is a G → A mutation in the Insulin-like growth factor 2 (IGF2) gene (which can be identified by the nt241(G-A) marker). The specification also indicates that the Swc9 marker is located in the 3'untranslated region of the IGF2 gene and further indicates that the genetic markers Swr2516, Swc9, S22623 and Swr783 are linked to the QTL such that the linkage is statistically significant ($P<0.001$). The specification describes the QTL as a "paternally imprinted" QTL because the offspring of the male pigs who inherit this QTL from their father have a decreased fat deposit compared to control pigs, regardless of the zygosity of the offspring. Therefore, if the male pig passes the QTL on to its offspring, the offspring inheriting the QTL from the father has decreased fat deposit regardless of the phenotype of the mother. It is noted that based on this description of "paternal imprinting" it would be possible for the genetic markers to be present on chromosome 2 of a pig, yet if the chromosome was not inherited from the father, the phenotype would not be imprinted because the specification has only described the QTL as a "paternally" imprinted QTL. Therefore, identifying that a pigs' chromosome 2 comprises the genetic markers described would not necessarily indicate that the pig had a paternally imprinted QTL as it would have to be determined if the chromosome was inherited from the mother or father. For example, a male pig that is homozygous for the QTL will pass the QTL to all of its offspring and all of the offspring will have decreased fat deposit because they inherited the paternally imprinted QTL from their father. The female offspring of that inherit the paternally imprinted QTL will also pass this QTL on to at least some of its offspring as well. However, since the QTL is paternally imprinted, inheritance of the QTL from the mother would necessarily result in decreased fat deposit in the offspring as it has not been shown that the QTL is maternally imprinted. In fact, the disclosure

that the QTL is paternally imprinted suggests that the QTL is not maternally imprinted. Therefore, identifying that a pig has the QTL on chromosome 2 would not necessarily indicate that the QTL is paternally imprinted in this pig because it is possible that the QTL was maternally inherited. It is noted that neither the claims nor the specification describe how to determine if a chromosome is a maternally or paternally inherited chromosome. As such, the specification has not provided an enabling disclosure for the instant claims because merely identifying that a pig has the QTL would not indicate that the QTL is paternally imprinted in the pig having the QTL. It is noted that the specification has provided a enabling disclosure for identifying a pig wherein chromosome 2 of the pig comprises the genetic markers associated with the QTL. Furthermore, the specification is enabling for identifying a pig having the indicated QTL at position 2p1.7 of chromosome 2, wherein if the pig is a male pig it can be used in a breeding program such that the offspring of the male pig that inherit the QTL from the male pig would have decreased fat deposit as the QTL is paternally imprinted in these offspring.

It is noted that the specification only appears to indicate that the QTL results in the phenotype that is decreased fat deposit. There does not appear to be any indication that the QTL is also associated with muscle mass. Therefore, the specification has only provided an enabling disclosure for a paternally imprinted QTL associated with decreased fat deposit. Additionally the specification does not disclose that the QTL is maternally imprinted, only that it is paternally imprinted. The specification also does not disclose that the QTL is present in any other species other than pigs.

Regarding the breadth of the claims, it is noted that claims 1, 2, 6, 8, 9 and 36 are drawn to a method for selecting an animal (i.e. any animal) having a parentally imprinted QTL (i.e. any

parentally imprinted QTL) associated with muscle mass and/or fat deposit. Claims 3, 4, and 7 indicate that the animal is a pig, but these claims encompass a pig having any parentally imprinted QTL associated with muscle mass and/or fat deposit. Claim 36 also encompasses "a functional fragment of said parentally imprinted QTL comprising genetic information capable of influencing a quantitative trait of said animal". Claims 39 and 40 encompass a method for selecting an animal (i.e. any animal) having desired muscle mass and/or fat deposit by associating the desired muscle mass and/or fat deposition trait with a parentally imprinted QTL (i.e. any parentally imprinted QTL). Claims 41-45 encompass a method for selecting a pig having a paternally imprinted QTL on chromosome 2 associated with a desired muscle mass and/or fat deposit by identifying the presence of the paternally imprinted QTL on chromosome 2 of the pig. Therefore, the claims are very broad and, in their broadest embodiments encompass selecting any animal having any parentally imprinted QTL associated muscle mass and/or fat deposit. With respect to claims 41-45, it is respectfully pointed out that the claims encompass selecting a pig (either a male or female pig) that has a paternally imprinted QTL on chromosome 2 that is associated with muscle mass and/or fat deposit.

However, the specification has not provided an enabling disclosure that is commensurate in scope with these claims.

The prior art does not appear to teach any parentally imprinted QTLs, considering that parental imprinting is defined as a phenomenon wherein the imprinted trait of one parent is preferably but gender-aspecifically expressed in his or her offspring. The phenomenon of parental imprinting gives rise to differential expression of paternally and maternally inherited alleles of certain genes due to sex-specific epigenetic differences inherited from the germline,

which is different from allelic "dominance" where a dominant allele affects the phenotype regardless if the animals are homozygous or heterozygous for the dominate allele and irrespective to maternal or paternal inheritance of the allele. It is noted that Applicants acknowledge this difference between dominance and parental imprinting in the communication filed 6/8/2005 (e.g., see page 13, first two paragraphs).

The prior art teaches that identification of a QTL associated with a particular phenotype in one species of animal is not indicative that the QTL will be correlated to the same phenotype in all species. For instance, **Pandya et al. (American Journal of Human Genetics 1994; previously cited)** teaches that although IGF-1 and IGF-2 (as well as there respective receptors) have been associated with body size in mice, there is "no evidence that the IGF-1 locus is imprinted in man". Therefore, the prior art teaches that the identification of a correlation of a phenotype and a QTL in one species does not indicate that there is a correlation between the phenotype and QTL in all species of animals.

Considering the breadth of the claims, the broadest claims encompass any QTL that is associated with muscle mass and/or fat in any animal. The specification, however, has only disclosed on such QTL, the QTL that is located at position 2p1.7 on pig chromosome 2 wherein the QTL is linked with the following genetic markers: nt241(G-A), Swc9, Swr2516, S22623 and Swr783 wherein when the pig has inherited this QTL from its father it is a paternally imprinted QTL.

Considering the teaching of the art of record it is clear that although a genetic element (e.g., a QTL) may be associated with a particular effect/phenotype in one species, does not necessarily indicate the same genetic element will be associated with the same effect in all

species of animals. Therefore, additional experimentation would have to be done in order to overcome indicated problems.

The level of the skill in the art is deemed to be high.

Considering the nature of the invention, the breadth of the claims, the unpredictable nature of the invention as recognized in the prior art, the limited amount of working examples and guidance provided, and the high degree of skill required to practice the invention, it is concluded that the specification does not provide an enabling disclosure for the full scope of instant claims. Therefore, additional experimentation is required before one of skill in the art could make and use the claimed invention. The amount of additional experimentation required to perform the broadly claimed invention is undue.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 recites the limitation "the parentally imprinted QTL" in line 14. There is insufficient antecedent basis for this limitation in the claim. It is noted that there is antecedent basis for "the paternally imprinted QTL". Claims 42-45 are rejected for the same reason as they are dependent claims.

Claim Objections

Claim 42 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 42 is drawn to the method of claim 41 further comprising testing a nucleic acid sample from the pig for the presence of the paternally imprinted QTL on chromosome 2. However, Claim 41 already requires the testing of a nucleic acid sample from the pig for the presence of the paternally imprinted QTL on chromosome 2 (e.g., see lines 4 and/or 11 of claim 41). Therefore it is unclear how claim 42 further limits claim 41.

Claim 41 is objected to because of the following informalities: claim 41 recites the phrase "the insulin like growth factor-2 (IGF2)" rather than "the insulin like growth factor-2 gene (IGF2)". This appears to be merely an omission of the word "gene" based on the use of the phrase "the insulin like growth factor-2 gene (IGF2)" throughout the claims (e.g., see claims 6, 44). Appropriate correction is required.

Response to Arguments

Applicant's arguments filed 12/27/05 have been fully considered by the Examiner. However, in light of the reconsideration of the evidence of record, a new ground(s) of rejection has been set forth for the reasons indicated above. It is respectfully pointed out that the claims were previously rejected under 35 USC 112, 1st paragraph and the Applicants have responded to

the previous rejection. However, the arguments do not specifically address the issues raised in the new rejection set forth above. Therefore, Applicants arguments are not persuasive to overcome the new rejection. Applicants argue that the specification discloses that a phenotype for the muscle mass and/or fat deposition in a pig is linked to a parentally imprinted QTL (e.g., at chromosome 2, specifically 2p1.7); the specification further discloses associating the phenotypic trait with the parentally imprinted QTL and mapping the QTL to chromosome 2 in the pig. (Specification, paragraph ([00262], Example 1, paragraph [00602]); and, the specification also discloses a nucleic acid sample obtained from the pig and tested for the presence of the paternally imprinted QTL on chromosome 2 of the pig; therefore, when the parentally imprinted quantitative trait locus is present in the nucleic acid sample, the animal is selected as having the desired trait. Applicants argue that when read in light of the specification, one of skill in the art would be able to select an animal having the desired phenotypic property by testing the animal for the presence of a paternally imprinted QTL identified according to the guidelines in the specification even if it requires a considerable amount of additional experimentation (see page 11 of the response filed 12/27/2005).

This is not persuasive because: (1) the specification does not appear to disclose evidence that the QTL is associated with anything other than decreased fat deposit; (2) the broad claims are not limited to pigs; (3) the specification has only provided evidence that the QTL is paternally imprinted, not parentally imprinted as claimed in the broad claims; (4) the broad claims are not limited to testing an animal for a paternally imprinted QTL, but encompass testing for a parentally imprinted QTL; and, (5) the amount of additional experimentation is considered to be beyond what one of skill in the art, at the time of filing, would consider routine. In fact, the

required experimentation is trial and error experimentation without any guarantee of identifying a parentally imprinted QTL associated with muscle mass and/or fat deposit in any non-pig animal, especially in light of the state of the art at the time of filing which is that there were no such parentally imprinted QTLs known.

Therefore, Applicants arguments are not persuasive.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON ANGELL
PATENT EXAMINER